

Food and Drug Administration, HHS

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522.1696b Penicillin G procaine aqueous suspension.
 522.1696c Penicillin G procaine in oil.
 522.1698 Pentazocine lactate injection.
 522.1704 Sodium pentobarbital injection.
 522.1720 Phenylbutazone injection.
 522.1820 Pituitary luteinizing hormone for injection.
 522.1850 Polysulfated glycosaminoglycan.
 522.1862 Sterile pralidoxime chloride.
 522.1870 Praziquantel.
 522.1881 Sterile prednisolone acetate aqueous suspension.
 522.1883 Prednisolone sodium phosphate.
 522.1884 Prednisolone sodium succinate injection.
 522.1885 Prednisolone tertiary butylacetate suspension.
 522.1890 Sterile prednisone suspension.
 522.1920 Prochlorperazine, isopropamide for injection.
 522.1940 Progesterone and estradiol benzoate.
 522.1962 Promazine hydrochloride.
 522.2002 Propiopromazine hydrochloride injection.
 522.2005 Propofol.
 522.2012 Prostalene solution.
 522.2063 Pyrilamine maleate injection.
 522.2076 Romifidine.
 522.2100 Selenium, vitamin E injection.
 522.2112 Sometribove zinc suspension.
 522.2120 Spectinomycin dihydrochloride injection.
 522.2121 Spectinomycin sulfate.
 522.2150 Stanozolol sterile suspension.
 522.2200 Sulfachlorpyridazine.
 522.2220 Sulfadimethoxine injection.
 522.2240 Sulfaethoxyypyridazine.
 522.2260 Sulfamethazine.
 522.2340 Sulfomyxin.
 522.2404 Thialbarbitone sodium for injection.
 522.2424 Sodium thiamylal for injection.
 522.2444 Sodium thiopental implantation or injectable dosage forms.
 522.2444a Sodium thiopental for injection.
 522.2444b Sodium thiopental, sodium pentobarbital for injection.
 522.2460 Tildipirosin.
 522.2470 Tiletamine hydrochloride and zolazepam hydrochloride for injection.
 522.2471 Tilmicosin.
 522.2474 Tolazoline hydrochloride injection.
 522.2476 Trenbolone acetate.
 522.2477 Trenbolone acetate and estradiol.
 522.2478 Trenbolone acetate and estradiol benzoate.
 522.2483 Triamcinolone.
 522.2582 Triflupromazine hydrochloride injection.
 522.2610 Trimethoprim and sulfadiazine.
 522.2615 Tripelennamine hydrochloride injection.
 522.2630 Tulathromycin.
 522.2640 Tylosin.
 522.2662 Xylazine.

522.2670 Yohimbine injectable.
 522.2680 Zeranol.
 522.2690 Zinc gluconate.

AUTHORITY: 21 U.S.C. 360b.

SOURCE: 40 FR 13858, Mar. 27, 1975, unless otherwise noted.

§ 522.23 Acepromazine.

(a) *Specifications.* Each milliliter of solution contains 10 milligrams (mg) acepromazine maleate.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter:

(1) No. 000010 for use as in paragraphs (d) and (e) of this section.

(2) No. 000859 for use as in paragraph (d) of this section.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use.* It is used in dogs, cats, and horses as follows:

(1) *Amount.* Dogs: 0.25 to 0.5 mg per pound (lb) of body weight; Cats: 0.5 to 1.0 mg/lb of body weight; Horses: 2.0 to 4.0 mg per 100 lbs of body weight.

(2) *Indications for use.* As a tranquilizer.

(e) *Conditions of use.* It is used in dogs as follows:

(1) *Amount.* Dogs: 0.25 to 0.5 mg/lb of body weight.

(2) *Indications for use.* As an aid in tranquilization and as a preanesthetic agent.

[75 FR 10167, Mar. 5, 2010; 78 FR 17597, Mar. 22, 2013]

§ 522.44 Sterile sodium acetazolamide.

(a) *Specifications.* Sterile sodium acetazolamide contains acetazolamide sodium complying with United States Pharmacopeia as a sterile powder with directions for reconstituting the product with sterile distilled water to furnish a product having a concentration of 100 milligrams acetazolamide activity per milliliter.

(b) *Sponsor.* See No. 010042 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used as an aid in the treatment of dogs with mild congestive heart failure and for rapid reduction of intraocular pressure.¹

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these

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(2) It is administered intramuscularly or intraperitoneally to dogs at a level of 5 to 15 milligrams per pound of body weight daily preferably administered in two or more divided doses.¹

(3) For use only by or on the order of a licensed veterinarian.¹

§ 522.52 Alfaxalone.

(a) *Specifications.* Each milliliter contains 10 milligrams (mg) alfaxalone.

(b) *Sponsor.* See No. 049480 in § 510.600(c) of this chapter.

(c) *Conditions of use in cats and dogs—*
(1) *Amount—(i) Cats—(A) Induction of general anesthesia.* Administer by intravenous injection over approximately 60 seconds or until clinical signs show the onset of anesthesia, 2.2 to 9.7 mg/kilogram (kg) for cats that did not receive a preanesthetic or 1.0 to 10.8 mg/kg for cats that received a preanesthetic.

(B) *Maintenance of general anesthesia following induction.* Administer an intravenous bolus containing 1.1 to 1.3 mg/kg to provide an additional 7 to 8 minutes of anesthesia in preanesthetized cats; a dose containing 1.4 to 1.5 mg/kg provides an additional 3 to 5 minutes anesthesia in unpreanesthetized cats.

(ii) *Dogs—(A) Induction of general anesthesia.* Administer by intravenous injection over approximately 60 seconds or until clinical signs show the onset of anesthesia, 1.5 to 4.5 mg/kg for dogs that did not receive a preanesthetic or 0.2 to 3.5 mg/kg for dogs that received a preanesthetic.

(B) *Maintenance of general anesthesia following induction.* Administer an intravenous bolus containing 1.2 to 1.4 mg/kg to provide an additional 6 to 8 minutes of anesthesia in preanesthetized dogs; a dose of 1.5 to 2.2 mg/kg provides an additional 6 to 8 minutes of anesthesia in unpreanesthetized dogs.

(2) *Indications for use.* For the induction and maintenance of anesthesia and for induction of anesthesia followed by maintenance with an inhalant anesthetic, in dogs and cats.

uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

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(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[77 FR 64717, Oct. 23, 2012]

§ 522.56 Amikacin.

(a) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) of amikacin as amikacin sulfate.

(b) *Sponsors.* See Nos. 000856 and 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—*
(1) *Amount.* 5 mg/pound (lb) of body weight twice daily by intramuscular or subcutaneous injection.

(2) *Indications for use.* For treatment of genitourinary tract infections (cystitis) caused by susceptible strains of *Escherichia coli* and *Proteus* spp. and skin and soft tissue infections caused by susceptible strains of *Pseudomonas* spp. and *E. coli*.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[76 FR 17338, Mar. 29, 2011, as amended at 78 FR 17597, Mar. 22, 2013]

§ 522.62 Aminopentamide hydrogen sulfate injection.

(a) *Chemical name.* 4-(Dimethylamino)-2,2-diphenylvaleramide hydrogen sulfate.

(b) *Specifications.* It is sterile and each milliliter of aqueous solution contains 0.5 milligram of the drug.

(c) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) It is intended for use in dogs and cats only for the treatment of vomiting and/or diarrhea, nausea, acute abdominal visceral spasm, pylorospasm, or hypertrophic gastritis.

NOTE: Not for use in animals with glaucoma because of the occurrence of mydriasis.

(2) Dosage is administered by subcutaneous or intramuscular injection every 8 to 12 hours, as follows:

Weight of animal in pounds	Dosage in milligrams
Up to 10	0.1
11 to 20	0.2
21 to 50	0.3
51 to 100	0.4
Over 100	0.5